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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,892	07/29/2003	Lingyu Zhu	10173-084-999	5561
20583	7590	11/26/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			MONDESI, ROBERT B	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 11/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,892

Applicant(s)

ZHU ET AL.

Examiner

Robert B Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21 and 39-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the amendment filed September 09, 2004.

Claims 39-68 are new. **Claims 1-68** are pending. **Claims 1-15 and 22-38** are withdrawn. **Claims 16-21 and 39-68** are under examination.

Withdrawal of Objections and Rejections

The rejection of **claims 16-21** under 35 U.S.C § 112, second paragraph is withdrawn.

The rejection of **claims 16-21** under 35 U.S.C § 101 as being drawn to non-statutory subject matter is withdrawn.

Maintenance of rejections

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 17 and 54-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Shackelford and Herbert.

This rejection was explained in the previous Office action.

Claims 54-56 are drawn to variations of the amounts of the composition of the claimed invention. The cited reference anticipates the composition of the invention regardless of the amount that is claimed, a larger or smaller amount of a known composition is still inherently the same composition and therefore in this case does not contribute to the novelty of the invention.

Claims 57-60 are merely variations of **claim 17** stating the various degrees of LCAT activation activity. The applicants are reminded, as mentioned below; functional language in view of the composition of the present application has not been given patentable weight. **Claims 65-68** are drawn to the various sources of the purified non-human animal ApoA-1 such as bovine, chicken, turkey and porcine and **claims 61-64** are drawn to a nonhuman ApoA-1 protein having greater than about 70%-90% homology with native human Apo A-I protein. The examiner would like to point out that the applicants have gone on the record stating that ApoA-1 has been identified in a number of non-human animals such as cows, chicken and guinea pigs (specification page 6, lines 21-32) and that Apo A-I derived from non-human animal species are of similar size and share considerable homology, for example Bovine Apo-I is 77% identical to human Apo-I (specification, page 6, lines 31-32; specification page 7, lines 7-9) and hen Apo-I differs from human Apo-I only by the presence of isoleucine (specification page 7, lines 19-21).

Claim Rejections - 35 USC § 103

Claims 16, 18-20 and 39-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shackelford and Herbert in view of Dasseux et al. US patent 6,037,323.

This rejection was explained in the previous Office action.

The applicants are reminded as mentioned below; functional language in view of the composition of the present application has not been given patentable weight.

Claims 39-45 are merely variations of **claim 16** stating the various degrees of LCAT

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activation activity. **Claims 46-49** are drawn to the various sources of the purified non-human animal ApoA-1 such as bovine, chicken, turkey and porcine and **claim 50-53** is drawn to a nonhuman ApoA-1 protein having greater than 70%-90% homology with native human Apo A-I protein. The examiner would like to point out that the applicants have gone on the record stating that ApoA-1 has been identified in a number of non-human animals such as cows, chicken, hen and guinea pigs (specification page 6, lines 21-32) and that Apo A-I derived from non-human animal species are of similar size and share considerable homology to human Apo A-I, for example Bovine Apo-I is 77% identical to human Apo-I (specification, page 6, lines 31-32; specification page 7, lines 7-9) and hen Apo-I differs from human Apo-I only by the presence of isoleucine (specification page 7, lines 19-21).

Response to applicant's arguments

Applicants assert that as amended claim 17 points out that the ApoA-I protein/lipid complex is capable of LCAT activation activity and cholesterol efflux and these features are highly relevant for medications used for the treatment of dyslipidemic disorders including cardiovascular disease.

In response to the applicants' assertions the examiner would like to state that the features of the composition that have been pointed out by the applicants fall under the category of functional language and are not given patentable weight. The applicants have not provided any new arguments as to how their composition is patentably distinct from the composition disclosed by Schackelford et al.

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In regards to the rejection of **claims 16 and 18-20** under 35 U.S.C 103(a) applicants assert that the cited references provide no teachings or suggestions that the ApoA-1 molecule from chicken could be used for the treatment of cholesterol disease in a human. However, applicants admit on the record that the cited references disclose an Apo-A1 protein derived from a nonhuman animal that is associated with a lipid.

Applicants are reminded that the claims are drawn to a composition and not a method of treatment therefore the intended use of the composition of the present application is not given patentable weight. The MPEP 2112.01 clearly states that, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the


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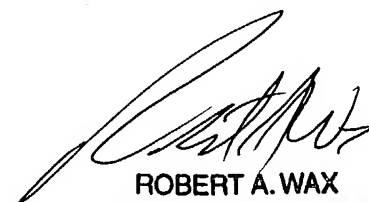
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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11-23-09


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